الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Mid-annual PV Inspection Report 2025

1st Jan 2025 until 30st Jun 2025

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1. Introduction

Between January 1 and June 30, 2025, the National Pharmacovigilance Center (NPC) at the Saudi Food & Drug Authority (SFDA) conducted a total of 21 pharmacovigilance inspections targeting Marketing Authorization Holders (MAHs) across various regions in the Kingdom. Types of Inspections Conducted: 6 Routine Inspections, 7 For-Cause Inspections, and 8 Re-Inspections. It is worth noting that two inspections were postponed upon request from MAHs, supported by acceptable justifications.

The report examines the types of inspections performed and the inspection findings, including an analysis of the specific topics where the inspection team found the highest number of findings. The purpose of these inspections was to evaluate the MAHs' compliance with existing Saudi pharmacovigilance regulations and guidelines. The MAHs were selected for inspection using a risk-based methodology, which follows the guidance in GVP Module III. This methodology considers factors such as:

- Product-specific risks (e.g., new active substances or new biological products)
- The complexity of the pharmacovigilance system
- The complexity and size of the organizations involved in the pharmacovigilance system, including service providers and the number of products
- The compliance and inspection history of an organization
- The reporting rate of the MAHs

The inspection types used by the inspection team are listed in Appendix I. The definitions for critical, major, and minor inspection findings are included in Appendix II.

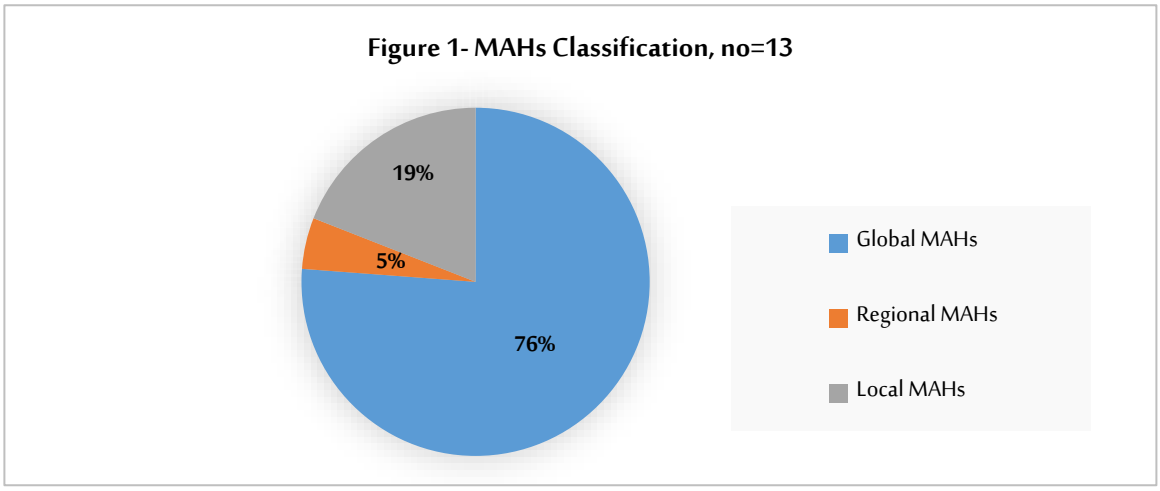
2. Overview

During the reported period, the NPC inspection team conducted a total of 21 pharmacovigilance inspections, classified as follows:

- 6 routine Pharmacovigilance Inspection.
- 7 Pharmacovigilance Inspection (For cause).
- 8 Pharmacovigilance Re-inspection.

3. Inspection Results of Routine and for cause inspections

Figure 1- MAHs Classification, no=13



As shown in Figure 1, out of the 21 pharmacovigilance inspections conducted by the National Pharmacovigilance Center (NPC) between January 1 and June 30, 2025, 7 were conducted for global MAHs, 1 for a regional MAH, and 4 targeted local pharmaceutical companies. This distribution reflects the NPC's ongoing efforts to monitor compliance across all levels of the pharmaceutical sector.

Inspection Results:

A total of 87 inspection findings were identified across the inspected MAHs during the reporting period .These findings were categorized based on their severity as follows:

- 7 Critical findings.
- 55 Major Findings.
- 25 Minor findings.

Figure 2- Inspection Results for Mid Annual 2025

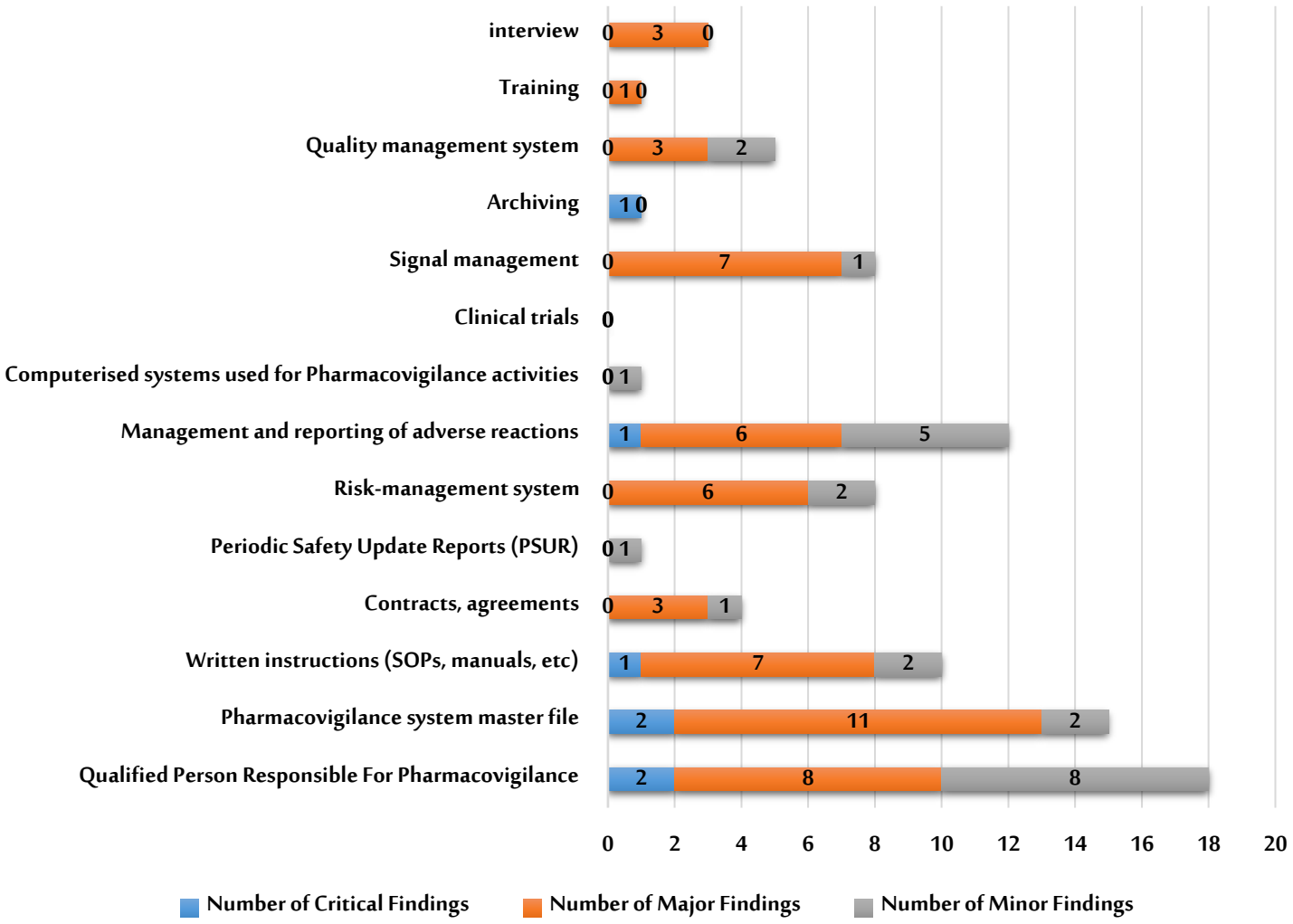


Table 1: Inspection Findings by Topic area and severity

Topic Areas	Critical Findings	Major Findings	Minor Findings
Qualified Person Responsible For Pharmacovigilance	2	8	8
Pharmacovigilance system master file	2	11	2
Written instructions (SOPs, manuals)	1	7	2
Contracts, agreements	0	3	1
Periodic Safety Update Reports (PSUR)	0	0	1
Risk-management system	0	6	2
Management and reporting of adverse reactions	1	6	5
Computerized systems used for Pharmacovigilance activities	0	0	1
Clinical trials	0	0	0
Signal management	0	7	1
Archiving	1	0	0
Quality management system	0	3	2
Training	0	1	0
Interview	0	3	0

The table above presents the distribution of critical, major, and minor findings identified by the NPC inspection team across various pharmacovigilance topic areas. The highest proportion of findings was related to the Qualified Person Responsible for Pharmacovigilance (QPPV), representing for 20.7% of the total observations. This was followed by deficiencies in the Pharmacovigilance System Master File (PSMF) (17.2%) and in written instructions such as SOPs and manuals (11.5%).

Common Areas of Findings:

I. Qualified person responsible for pharmacovigilance (QPPV).

This area represented for the highest proportion of finding, representing 20.7 % of all findings during inspections.

Figure 3- Qualified Person Responsible For Pharmacovigilance, no=18

II. Pharmacovigilance system master file (PSMF)

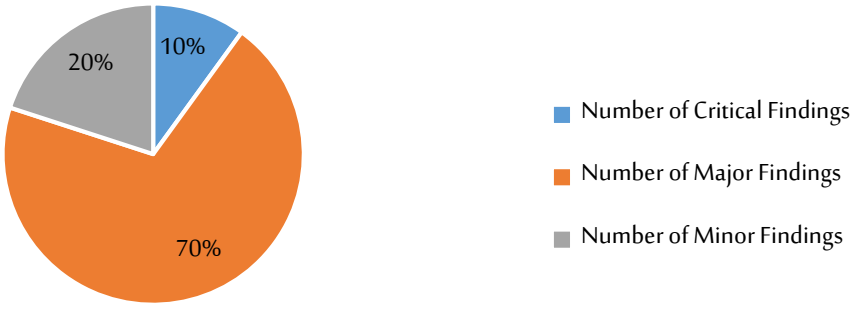
This area represented 17.2% of all inspection findings, making it the second most common area of non-compliance.

Figure 4 - Pharmacovigilance system master file, no=15

III. Written instructions (SOPs, manuals)

This area represented 11.5% of all inspection findings.

Figure 5- Written instructions (SOPs, manuals), no =10



During the reporting period from January 1 to June 30, 2025, inspection data were collected from 7 global pharmaceutical companies, and 4 local pharmaceutical companies. Additionally, 1 inspection was conducted at a regional pharmaceutical company, where several findings were also identified. Notably, the number of inspection findings increased significantly compared to the previous mid annual report of 2024. This increase may be attributed to several contributing factors, referred to as:

1. Regulatory Misalignment.
    - Incomplete understanding or misinterpretation of the new regulatory requirements.
    - Local SOPs were not updated to reflect recent changes.
    - Lack of clear procedures for ICSR submission, quality reporting, and follow-up activities.
    - Insufficient awareness among local QPPVs regarding submission timelines and obligations.
2. Deficiencies in Adverse Drug Event (ADE) Reporting Systems.
    - Absence of dedicated Arabic-language platforms (e.g., website or landline) for public reporting of adverse events.
    - Restricted access for the local QPPV to the global safety database and lack of coordination with the local field force to collect cases effectively.
    - The local QPPV was not properly engaged in pharmacovigilance tasks, resulting in limited oversight, delayed responses, and miscommunication between the local QPPV and the global PV Team.

4. Engaging the stakeholders in Saudi GVP update

In 2024, the NPC inspection team organized three dedicated workshops targeting all Qualified Persons Responsible for Pharmacovigilance (QPPVs) and their deputies. The primary objective of these sessions was to enhance awareness of the updated Saudi Good Pharmacovigilance Practices (GVP) and to address practical challenges encountered by QPPVs in fulfilling their regulatory roles. The sessions provided an overview of the new timeframes for pharmacovigilance activities and the legislative changes introduced in the revised guidelines.

The workshops also served as a forum to identify knowledge gaps and discuss practical challenges encountered by attendees in their daily operations. Representatives from the National Pharmacovigilance Center (NPC) participated to provide clarification on departmental updates and to address any queries or concerns raised

during the sessions. This approach ensured that the workshops successfully contributed to enhancing attendees' knowledge and addressing their professional challenges.

5. Re-Inspection Outcomes

Out of the 8 re-inspections conducted during the reporting period (January 1 – June 30, 2025), the following outcomes were observed:

- 6 MAHs successfully addressed the previously identified findings and were considered compliant during the re-inspection visit.
- Two MAHs did not perform well during the re-inspection, as they failed to implement the proposed Corrective and Preventive Actions (CAPAs). As a result, their cases were escalated to the legal department for further regulatory action by the Saudi FDA. This step was taken due to repeated non-compliance and lack of commitment to previous inspection outcomes.

6. Summary

During the reporting period, the inspection team carried out a total of 21 pharmacovigilance inspections, comprising 6 routine inspections, 7 for-cause inspections, and 8 re-inspections. Among these, 12 inspections targeted Marketing Authorization Holders (MAHs), including 7 global MAHs, 4 local MAHs, and 1 regional MAH. A total of 87 findings were identified across all inspections conducted during the reporting period, including 7 critical, 55 major, and 25 minor findings. This distribution reflects varying levels of non-compliance, with the majority of issues falling under the major category, highlighting the need for focused and timely corrective actions by the inspected entities. The highest proportion of findings were related to the Qualified Person Responsible for Pharmacovigilance (QPPV), accounting for 20.7% of all observations. This was followed by deficiencies in the Pharmacovigilance System Master File (PSMF), which represented 17.2%, and issues in written instructions, including SOPs and manuals, comprising 11.5% of the total.

Compared to the previous Mid annual report, the number of reported inspection findings increased, which may be attributed to several factors, including a lack of understanding or misapplication of the updated regulatory requirements, outdated SOPs that do not reflect the latest Saudi GVP guidelines, and missing or unclear job descriptions outlining local pharmacovigilance responsibilities. Among the 8 re-inspections conducted, 6 MAHs successfully resolved their previously identified issues and were deemed compliant, while 2 MAHs were

escalated to the legal track due to unsatisfactory performance and failure to implement the required corrective actions. To support MAHs in adapting to these changes, the NPC organized a series of workshops in 2025 for QPPVs and their deputies. These sessions aimed to identify key gaps, address operational challenges in applying the Saudi GVP, and provide clarity on the updated timeframes and legislative changes introduced in the revised guidelines.

By implementing the Saudi GVP regulations, MAHs across all levels (Global, regional, and local) can strengthen their pharmacovigilance systems, ensure regulatory compliance, and ultimately contribute to enhancing drug safety for patients in Saudi Arabia.

7. Trend analysis and root causes of increased findings in 2025.

Compared to the 2024 mid annual report, the number of pharmacovigilance inspection findings in 2025 increased by approximately 48%, rising from 59 findings in 2024 to 87 in 2025. While the numbers did not return to the 2023 peak (167 findings), this analysis reflects several contributing factors:

- **Regulatory transition challenges:** The implementation of Saudi GVP Version 3.1 introduced new requirements. Many MAHs struggled with outdated or missing SOPs, misunderstanding of the updated guidelines, and insufficient updates to the PSMF/PSSF, which led to non-compliance in core areas.
- **Insufficient QPPV involvement:** In multiple cases, the local QPPV was not properly engaged in pharmacovigilance operations. This resulted in poor oversight, lack of accountability, and delayed or incomplete reporting to the global safety units.
- **Inadequate local reporting systems:** Several companies lacked dedicated Arabic language reporting tools (e.g., public websites or landlines), and had no structured system for logging or managing locally received adverse event reports from public.
- **Follow-Up inspections revealed persistent gaps:** Of the 8 re-inspections conducted in 2025, 2 MAHs failed to implement their corrective actions and were escalated to the legal SFDA Department. This indicates that some compliance issues were not resolved despite previous warnings, contributing to the overall increase in findings.
- **Absence of internal performance monitoring tools:** The absence of key performance indicators (KPIs) and structured monitoring frameworks within certain MAHs may have contributed to delayed or inadequate implementation of corrective actions.

- **Expanded inspection coverage of local and regional MAHs:** In 2025, more inspections were conducted at local and regional pharmaceutical companies. Some of these companies had less developed pharmacovigilance systems compared to global companies. Because they were not inspected as frequently in the past, their issues were not fully visible in previous reports. The increased focus on these companies in 2025 revealed new or recurring problems that helped explain the rise in findings.

Appendix I: Inspection definitions

**excerpt from page 100-105 of the Guideline on Good Pharmacovigilance Practices (GVP) (Version 3.1, January2023).*

Routine inspections

Routine pharmacovigilance inspections are inspections scheduled in advance as part of inspection programs. There is no specific trigger to initiate these inspections, although a risk-based approach to optimize supervisory activities should be implemented. These inspections are usually system inspections but one or more specific products may be selected as examples to verify the implementation of the system and to provide practical evidence of its functioning and compliance. Particular concerns, e.g. raised by assessors, may also be included in the scope of a routine inspection, in order to investigate the specific issues.

'For cause' inspections

For-cause pharmacovigilance inspections are undertaken when a trigger is recognized, and an inspection is considered an appropriate way to examine the issues. For-cause inspections are more likely to focus on specific pharmacovigilance processes or to include an examination of identified compliance issues and their impact for a specific product. However, full system inspections may also be performed resulting from a trigger.

Pre- authorization inspections

Pre-authorization pharmacovigilance inspections are inspections performed before a marketing authorization is granted. These inspections are conducted with the intent of examining the existing or proposed pharmacovigilance system as it has been described by the applicant in support of the marketing authorization application. Pre-authorization inspections are not mandatory, but may be requested in specific circumstances. Principles and procedures for requesting pre-authorization inspections should be developed to avoid performing unnecessary inspections which may delay the granting of a marketing authorization.

Announced and unannounced inspections.

It is anticipated that the majority of inspections will be announced i.e. notified in advance to the inspected party, to ensure the availability of relevant individuals for the inspection. However, on occasion, it may be appropriate to conduct unannounced inspections or to announce an inspection at short notice (e.g. when the

announcement could compromise the objectives of the inspection or when the inspection is conducted in a short timeframe due to urgent safety reasons).

Remote inspections

These are pharmacovigilance inspections performed by inspectors remote from the premises of the marketing authorization holder or firms employed by the marketing authorization holder. Communication mechanisms such as the internet or telephone may be used in the conduct of the inspection. This approach may also be taken where there are logistical challenges to an on-site inspection during exceptional circumstances (e.g. a pandemic outbreak or travel restrictions). Such approaches are taken at the discretion of the inspectors and in agreement with the body commissioning the inspection. The logistical aspects of the remote inspection should be considered following liaison with the marketing authorization holder.

Re-inspections

A re-inspection may be conducted on a routine basis as part of a routine inspection program. Risk factors will be assessed in order to priorities re-inspections. Early re-inspection may take place where significant non-compliance has been identified and where it is necessary to verify actions taken to address findings and to evaluate ongoing compliance with the obligations, including evaluation of changes in the pharmacovigilance system. Early re-inspection may also be appropriate when it is known from a previous inspection that the inspected party had failed to implement appropriately corrective and preventive actions in response to an earlier inspection.

Appendix II: Inspection finding definitions

**excerpt from page 127-128 of the Guideline on Good Pharmacovigilance Practices (GVP) (Version 3.1, January2023).*

Critical deficiency

Is a fundamental weakness in one or more pharmacovigilance processes or practices that adversely affects the whole pharmacovigilance system and/or the rights, safety or well-being of patients, or that poses a potential risk to public health and/or represents a serious violation of applicable regulatory requirements.

Major deficiency

Is a significant weakness in one or more pharmacovigilance processes or practices, or a fundamental weakness in part of one or more pharmacovigilance processes or practices that is detrimental to the whole process and/or could potentially adversely affect the rights, safety or well-being of patients and/or could potentially pose a risk to public health and/or represents a violation of applicable regulatory requirements which is however not considered serious.

Minor deficiency

Is a weakness in the part of one or more pharmacovigilance processes or practices that is not expected to adversely affect the whole pharmacovigilance system or process and/or the rights, safety or well-being of patients.

Deficiencies are classified by the assessed risk level and may vary depending on the nature of medicine. In some circumstances, an otherwise major deficiency may be categorized as critical. A deficiency reported after a previous inspection and not corrected may be given higher classification

Appendix III: Categorization of finding

Table 2: Topics and sub-topics of inspection findings

Topic area	**Sub-topic of reported findings**
Qualified Person Responsible For Pharmacovigilance	Qualifications
	Job description
	System oversight
	Back-up process and delegation
Pharmacovigilance system master file	Organizational structure
	Pharmacovigilance system
	Maintenance and submission
Written instructions (SOPs, manuals, etc.)	Procedures
	Manuals
	Process for SOP training
Contracts, agreements	Contracts
	Agreements
Periodic Safety Update Reports (PSUR)	PSUR scheduling
	Format and content
	Quality control of PSURs
	Timeliness of submission
	Assessment report comments
Risk-management system	Risk-management plan format and content
	Compliance with risk minimization measures which are beyond routine Pharmacovigilance
Management and reporting of adverse reactions	Data collection methods
	Assessments of seriousness, causality and expectedness
	Medical review
	Quality control process
	Submissions and follow up processes
	Literature screening

Computerized systems used for Pharmacovigilance activities	Backup and disaster recovery process
Clinical trials	Adverse event reporting from clinical trials
	Consistency between the Investigator's Brochure and SPC when marketed products are used in CT
Signal management	Dataset used for conducting signal detection (inclusion of information from all relevant sources)
	Periodicity of data review
	Signal validation process
Archiving	Archiving facilities
Quality management system	Quality system and compliance management
	Facilities and equipment for pharmacovigilance
	Audit (internal- and external) and Corrective and Preventive Actions process
Training	Available trainings
	Evaluation of training
	Maintenance of training records
Interview	MAH employees interview

Appendix V: Abbreviations

ADR	Adverse Drug Reaction
AE	Adverse Event
aRMM	Additional Risk Minimisation Measure
CAPA	Corrective and Preventative Action
GVP	Good Pharmacovigilance Practice
ICSR	Individual Case Safety Report
MAH	Marketing Authorisation Holder
NPC	National Pharmacovigilance Center
PSMF	Pharmacovigilance System Master File
PSSF	Pharmacovigilance Sub-System File
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
QPPV	Qualified Person responsible for Pharmacovigilance
RMP	Risk Management Plan
SFDA	Saudi Food & Drug Authority
SOP	Standard Operation Procedures